DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-337/S-013

Merck & Co., Inc.
Attention: Sandra J. Rattray, Ph.D.
Associate Director, Regulatory Affairs
P.O. Box 2000, RY 33-200
Rahway, New Jersey 07065

Dear Dr. Rattray:

Please refer to your supplemental new drug application dated October 29, 2003, received October 30, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVANZ™ (Ertapenem Sodium).

We acknowledge receipt of your submissions dated March 29, 2004 and April 16, 2004.

This "Changes Being Effected" supplemental new drug application provides for the addition of a new subsection entitled "Post-Marketing Experience" to include "anaphylaxis including anaphylactoid reactions" and "hallucinations" based on WAES reports.

We completed our review of this application and as agreed in your correspondence of April 16, 2004, the additional revisions to the *Post-Marketing Experience* subsection (see below) as outlined in the FDA's facsimile of April 14, 2004, are acceptable. Therefore, this application, as amended, is approved, effective on the date of this letter.

Post-Marketing Experience:

The following post-marketing adverse experiences have been reported:
Immune System: anaphylaxis including anaphylactoid reactions
Nervous System & Psychiatric: hallucinations

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted April 16, 2004, #9500001).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated **"FPL for approved supplement NDA 21-337/S-013"**. Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Maureen Dillon-Parker, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice Soreth, M.D.
Director
Division of Anti-Infective Drug Products, HFD-520
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Janice Soreth

4/30/04 11:59:38 AM